

## **REMARKS**

Reconsideration and withdrawal of the examiner's rejections under 35 U.S.C. §§ 102 and 103 is respectfully requested in view of the above amendments and the following remarks. The applicant would like to thank the examiner for his time and kind cooperation in this matter.

### ***35 USC § 102 and § 103***

The examiner has rejected claims 1-10 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over GB 1 190 023. Applicants respectfully traverse this rejection.

GB '023 relates to a liquid biodegradable detergent composition based on alkali metal fatty soap and generically discloses the fact that the composition may contain at least one C<sub>8</sub> to C<sub>22</sub> unsaturated fatty acid (see page 1, line 19).

Applicants respectfully submit that a proper prima facie case under §§ 102 or 103 has not been made out at least because there is no specific disclosure of castor oil or ricinoleic acid unsaturated soaps nor the specific concentration range claimed of 0.05 to 4% by wt. for these components. However, to further distinguish the instant claims from GB '023, applicants have amended independent claim 1 to require that the unsaturated fatty acid soap component must consist essentially of castor oil or ricinoleic acid soap. Support for this amendment is found page 7, lines 17-18. Castor oil contains approximately 87% ricinoleic acid (d-12 OH oleic acid) and some stearic acid (Merck Index 13<sup>th</sup> ed., see attached)).

It has been unexpectedly found by way of the present invention (see examples) that a small amount of soap made from castor oil based fatty acids, their precursors or derivatives in a C<sub>12</sub>-C<sub>18</sub> soap matrix ensures high transparency in the composition, and allows for a wider formulation window such as the higher use of sodium soaps, lower use of non-soap detergents and humectants, and use of higher molecular weight fatty acid soaps. Applicant's respectfully submit that the unexpected results disclosed in the examples is sufficient to rebut the examiner's prima facie case assuming arguendo that a proper prima facie case had been made out. KSR v. Teleflex, 127 S.Ct. 1727 (2007). MPEP 716.02(a).

Claim 1 has been further amended to be commensurate with the scope of the fatty acid soaps actually used in the examples.

The examiner has rejected claims 1-10 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over GB 2 005 297. Applicants respectfully traverse this rejection. Applicants respectfully submit that GB '297 does not remedy the deficiencies of GB '023 with respect to the specific and essential unsaturated fatty acids now claimed.

The examiner has rejected claims 1-10 under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 2006/045390. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the subject matter of WO '390 and the instant invention were, at the time the claimed invention was made, subject to an obligation of assignment to the same person, i.e., Unilever PLC, Unilever NV, Hindustan Unilever Limited and Conopco, Inc., d/b/a Unilever. Therefore, the WO '390 reference is disqualified as 102(e), 103(a) reference (MPEP 706.02 (I)(1)).

#### ***Double Patenting***

The examiner has provisionally rejected claims 1-10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/255,378. In response, applicants herewith submit a terminal disclaimer for Application No. 11/255,378.

#### ***Other Amendments***

Claims 9 and 10 have been amended to conform the process claims to the proper format.

### CONCLUSION

In summary, claims 1, 2, 4, 9 and 10 have been amended. No new matter has been added.

In light of the above remarks, applicants submit that the claims now pending in the present application is in condition for allowance. Reconsideration and allowance of the application is respectfully requested. The examiner is invited to contact the undersigned if there are any questions concerning the case.

Respectfully submitted,

A handwritten signature in cursive script, reading "Alan A. Bornstein".

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*Am. J. Med. Sci.* 178, 748, 104 (1929); 106, 503 (1930); *Grass et al., Science* 115, 101 (1952); Heinle *et al., Trans. Assoc. Am. Phys.* 65, 214 (1952); Latner *et al., Biochem. J.* 55, XXIII (1953); Callender *et al., Brit. Med. J.* 1, 10 (1954); Laner *et al., Lancet* I, 497 (1954); Baum, Federman, US 2912360 (1959 to Lilly). Purification: Robbins, US 3008877 (1961 to Armour); Higley, Ellenbogen, US 343927 and US 3591678 (1969, 1971, both to Am. Cyanamid). In approx 30% of pernicious anemia patients, antibodies are produced in the serum which combine with IF, thus inhibiting its biological activity. In clinical tests diminished excretion of vitamin B<sub>12</sub> in the feces is taken as evidence of intrinsic factor activity. Function in the metabolism of vitamin B<sub>12</sub>: *Glass, Physiol. Rev.* 43, 529 (1963). *Review: Gräbeck, Progr. Hematol.* 6, 233 (1969).

#### Combination with vitamin B<sub>12</sub>—Gastrin

THERAP CAT: Adjuvant in vitamin B<sub>12</sub> utilization.

**1908. Castor Oil.** Ricinus oil: oil of Palma Christi; tang-anang oil; Neolind. Fixed oil obtained by cold-pressing the seeds of *Ricinus communis* L., *Euphorbiaceae*. Triglyceride of fatty acids. Fatty acid composition is approx ricinoleic 87%, oleic 7%, linoleic 3%, palmitic 2%, stearic 1% and dihydroxy-stearic trace amounts: Binder *et al., J. Am. Oil Chem. Soc.* 39, 513 (1962). Review and bibliography: Anderson, *J. Philippine Pharm. Assoc.* 42, 5-16 (1955); Dominguez *et al., J. Chem. Ed.* 20, 446 (1952); F. C. Naughton *et al., in Kirk-Othmer Encyclopedia of Chemical Technology* vol. 5 (Wiley-Interscience, New York, 3rd ed., 1979) pp 1-15.

Pale yellow, viscous oil. Slight somewhat characteristic odor. The crude oil tastes slightly acid with a decidedly nauseating after-taste. Has excellent keeping qualities, does not turn rancid unless subjected to excessive heat. Dextrorotatory (undil. in sodium light),  $d_{20}^{25}$  0.961-0.963. Wt of tech grades: 8.1 to 8.9 lbs/gallon.  $n_D^{25}$  1.473-1.477.  $n_D^{20}$  1.466-1.473. Solidif  $-10^\circ$  to  $-18^\circ$ . Viscosity at 25°: 6-8 poises, also expressed as  $U \pm \frac{1}{2}$  (Gardner-Holdt Scale). Flash pt 445°F (230°C); ignition temp 840°F (449°C). Surface tension (dynes/cm): at 20° 39.0; at 80° 35.2. Acid value <4. Sapon no. 176-187. Iodine no. (Wijs) 81-91. Reichert-Meissl value <0.5. Polenske value <0.5. Acetyl value 144-150. Hydroxyl value 161-169. Miscible with abs ethanol, methanol, ether, chloroform, glacial acetic acid. Dissolves in its own vol of petr ether or 95% alcohol. Does not dissolve to any extent in mineral oil, unless mixed with another vegetable oil. When heated to 300° for several hours it polymerizes and becomes miscible with mineral oil.

USE: As an industrial raw material for the prepn of chemical derivs used in coatings, urethane derivs, surfactants and dispersants, cosmetics, lubricants; chief raw material for the production of sebacic acid, a basic ingredient in the production of synthetic resins and fibers; as lubricant in metal drawing, machine lubrication and 2-cycle engine fuels, in hydraulic fluids, rubber preservative and mold lubricants; constituent of embalming fluids; in soap manuf; to impart emollient and lubricant properties to cosmetic preps; as Turkey-red oil (sulfated castor oil) for dyeing and finishing textiles; as dehydrated castor oil in alkyds, resinous copolymers, varnishes, oil-based paints, enamels, calks and putties; as blown oil (oxidized oil) for plasticizing oilcloth, artificial leather, coated fabrics, and lacquers; to plasticize rosin in the manuf of sticky fly-paper, for nitrocellulose and similar coating systems, hot melts, duplicating and stencil inks, adhesives and laminants; as release and anti-sticking agent in hard candy manuf.

THERAP CAT: Cathartic.

THERAP CAT (VET): Mild purgative, but considered unreliable in adult horses. Emollient.

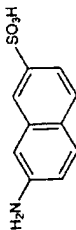
**1909. Castor Oil, Hydrogenated.** Opalwax; Castorwax. Mol wt about 932. A hard, white wax, mp 86-88°. Iodine num-

Consult the Name Index before using this section.

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Dyesuff intermediate.

**1903. Cassella's Acid F.** (494-44-0) 7-Amino-2-naphthalenesulfonic acid; 2-naphthylamine-7-sulfonic acid;  $\beta$ -naphthylamine-8-sulfonic acid.  $C_{10}H_7NO_2S$ ; mol wt 223.25. C 63.30%, H 4.06%, N 6.27%, O 21.50%, S 14.36%. Prepn by sulfonation of  $\beta$ -naphthylamine and separation from the 6-amino isomer: Green, *J. Chem. Soc.* 55, 33 (1889); from 7-hydroxy-2-naphthalenesulfonic acid and ammonia: Green, *loc. cit.* Wait, US 1492497 (1924).



**Monohydrate.** Crystals. Sol in 5040 parts cold water, 350 parts boiling water; sol in glacial acetic acid. Copper salt. Orange-yellow crystals. Sparingly sol in water: Ref: Green, Vakil, *J. Chem. Soc.* 113, 35 (1918).

**Note: Bronner's acid** was first described as 6-amino-2-naphthalenesulfonic acid or 2-naphthylamine-6-sulfonic acid. However, this product obtained by sulfonation of  $\beta$ -naphthylamine, was subsequently shown to be a mixture of about equal parts of 6- and 7-amino-2-naphthalenesulfonic acids: Green, *loc. cit.*

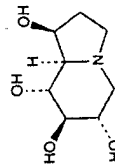
USE: Both the title compd and its 6-amino isomer are used in the manuf of azo dyes, e.g., GB 810246 (1959 to Bayer).

**1904. Cassia Fistula.** Cassia pods; drumstick; Indian laburnum; pudding-stick; pudding pipe; purging cassia. Dried fruit of *Cassia fistula* L. (*Cathartocarpus fistula* (L.) Pers.), *Leguminosae*. Habit. Upper Egypt, E. India; cultivated in tropical America and Africa. The pulp of the ripe fruit, *cassia pulp*, is almost black, viscid mass with a sweetish taste. *Constit.* Hydroxymethylanthraquinones, gum, tannin, albuminoids, about 60% sugars.

THERAP CAT: Cathartic.

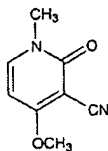
**1905. Castanea.** Chestnut. Leaves of *Castanea denata* (Murr.) Borkh., *Fagaceae*, collected in September and October, *Habit.* Southern Europe. There are hardly any chestnut trees left in the U.S. *Constit.* Tannin, gum, albumin, resin.

**1906. Castanospermine.** (79831-76-8) (1S,6S,7R,8R,8aR)-Octahydro-1,6,7,8-indolizinetriol; 1,6,7,8-tetrahydro-8a-indolizinetriol; (1S,6S,7R,8R,8aR)-1,6,7,8-tetrahydro-8a-indolizinetriol;  $C_{14}H_{21}NO_3$ ; mol wt 189.21. C 50.78%, H 7.99%, N 7.40%, O 33.82%. Polyhydroxy alkaloid isolated from the seeds of the Australian leguminous tree, *Castanospermum australe*, inhibits enzymatic glycoside hydrolysis. Isom of the naturally occurring (+)-form: L. D. Hohenschütz *et al., Phytochemistry* 20, 811 (1981). Total synthesis and absolute configuration: R. C. Bernotas, B. Ganem, *Tetrahedron Letters* 25, 165 (1984). Alternate synthesis: H. Hamana *et al., J. Org. Chem.* 52, 5492 (1987). Inhibition of  $\alpha$ - and  $\beta$ -glucosidases: R. Saul *et al., Arch. Biochem. Biophys.* 221, 593 (1983); *idem, ibid.* 230, 668 (1984). Insect antifeedant activity: D. L. Dreyer *et al., J. Chem. Ecol.* 11, 1045 (1985). Inhibition of HIV infection *in vitro*: B. D. Walker *et al., Proc. Natl. Acad. Sci. USA* 84, 8120 (1987). R. A. Gruters *et al., Nature* 330, 74 (1987).



## Rifalazil

8298



**Caution:** Ingestion may cause nausea, vomiting, hemorrhagic gastroenteritis, hepatic and renal damage, convulsions, coma, hypotension, respiratory depression, death.

**8295. Ricinoleic Acid.** [141-22-0] (9Z,12R)-12-Hydroxy-9-octadecenoic acid; d-12-hydroxyoleic acid.  $C_{18}H_{34}O_3$ ; mol wt 298.46. C 72.44%, H 11.48%, O 16.08%.  $CH_3(CH_2)_5CH(OH)CH_2CH=CH(CH_2)_7COOH$ . Found primarily in oils from the seeds of *Ricinus* spp. *Euphorbiaceae*. Accounts for about 90% of the triglyceride fatty acids of castor oil, and up to about 40% of the glyceride fatty acids of ergot oil. Bibliography on its isola: Ralston, *Fatty Acids* (New York, 1948) p 189. Also isolated from *Linum mucronatum* (flax), *Linaceae*: Kleiman, Spencer, *Lipids* 6, 962 (1971). Structure: Goldsobel, *Ber.* 27, 1121 (1894). Mechanism of biosynthesis: Morris, *Biochem. Biophys. Res. Commun.* 29, 311 (1967).

Liquid.  $d_4^{25}$  0.940; mp +5.5°; bp<sub>10</sub> 245°.  $[\alpha]_D^{25}$  +6.67°;  $n_D^{20}$  +7.15° (c = 5 in acetone).  $n_D^{20}$  1.4716. Neutralization value 187.98; iodine value 85.05. Sol in alcohol, acetone, ether, chloroform (cf. the solubilities of castor oil).

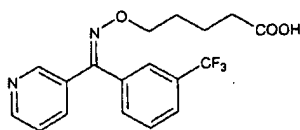
**Acid sulfate.** Ricinolsulfuric acid.  $C_{18}H_{34}O_6S$ . Obtained by reaction of chlorosulfonic acid. Viscous brown liquid with weak blue fluorescence. Sol in water (about 10%), alcohol, ether, chloroform.

**Sodium salt.** [5323-95-5] Soricin; Colidosan. Sodium salts of the fatty acids from castor oil. White or slightly yellow, odorless or almost odorless powder. Sol in water or alcohol. The solution is alkaline.

**USE:** In textile finishing; sometimes added to Turkey red oil, cleaning soaps.

**THERAP CAT:** Has been used in contraceptive jellies. The sodium salt has been used as sclerosing agent.

**8296. Ridogrel.** [110140-89-1] 5-[[[(E)-[3-Pyridinyl]-[3-(4-chloromethyl)phenyl]methylene]amino]oxy]pentanoic acid; 158070.  $C_{18}H_{17}F_3N_2O_3$ ; mol wt 366.33. C 59.02%, H 4.68%, N 15.56%, F 7.65%, O 13.10%. Combined thromboxane  $A_2$  synthase inhibitor and thromboxane  $A_2$ /prostaglandin endoperoxide receptor antagonist. Prepn: E. J. E. Freyne et al., *EP* 16601; *idem*, US 4963573 (1987, 1990 both to Janssen). Chemical pharmacology: B. Hoet et al., *Thromb. Haemostas* 68, 127 (1990); C. Weber et al., *ibid.* 68, 214 (1992). Clinical use in peripheral arterial obstructive disease: J. De Cree et al., *Int. Angiol.* 12, 59 (1993); as adjunct to thrombolysis in acute myocardial infarction: RAPT Investigators, *Circulation* 88, 588 (1994).

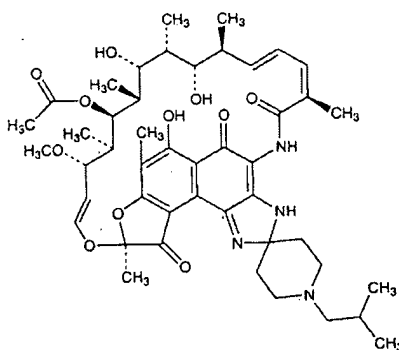


Crystals from diisopropyl ether/hexane (2:1), mp 70.3°.

**THERAP CAT:** Antithrombotic.

**8297. Rifabutin.** [72559-06-9] 1',4-Didehydro-1-deoxy-1,4-dihydro-5'-(2-methylpropyl)-1-oxorifamycin XIV; (9S,12E,26R,27S,28E)-5,12,21,23,25-pentahydroxy-10-(4-isobutyl-1-piperazinyl)-27-methoxy-2,4,16,20,22,24,26-heptamethyl-2,7-(epoxypentadeca[1,11,13]trienimino)-2H-furo[2,3-b]naphth[1,2-d]imidazole-2,4'-piperidine-5,10,26-trione-16-acetate; 4-deoxy-3,4-[2-spiro-(N-isobutyl-4-piperidyl)-rifamycin S; LM-427; Ansapipine; Mycobutin.  $C_{51}H_{74}N_4O_{11}$ ; mol wt 847.00. C 65.23%, H 7.38%, N 6.61%,

O 20.78%. Semisynthetic derivative of rifamycin S that inhibits nucleic acid synthesis. Prepn: L. Marsili et al., *DE* 2825445 (1979 to Farmitalia); *idem*, US 4219478 (1980 to Archifar Labs). *In vitro* and *in vivo* antibacterial activity: A. Sanfilippo et al., *J. Antibiot.* 33, 1193 (1980); C. Della Bruna et al., *ibid.* 36, 1502 (1983). Mechanism of action: D. Ungheri et al., *Drugs Exp. Clin. Res.* 10, 681 (1984). Comparative *in vitro* antimycobacterial spectrum: J. M. Dickinson, D. A. Mitchison, *Tubercle* 68, 177 (1987). *In vitro* inhibition of HIV-1 replication: R. Anand et al., *Antimicrob. Ag. Chemother.* 32, 684 (1988). Clinical pharmacokinetics: M. H. Skinner et al., *ibid.* 33, 1237 (1989). Pharmacology and clinical efficacy in mycobacterial infections: R. J. O'Brien et al., *Rev. Infect. Dis.* 9, 519 (1987).



Violet-red crystalline powder. Highly sol in chloroform, sol in methanol, slightly sol in ethanol, minimally sol in water. uv max (methanol): 493, 315, 274, 238 nm.

**THERAP CAT:** Antibacterial (tuberculostatic).

**8298. Rifalazil.** [129791-92-0] 1',4-Didehydro-1-deoxy-1,4-dihydro-3'-hydroxy-5'-(4-(2-methylpropyl)-1-piperazinyl)-1-oxorifamycin VIII; (2S,16Z,18E,20S,21S,22R,23R,24R,25S,26R,27S,28E)-5,12,21,23,25-pentahydroxy-10-(4-isobutyl-1-piperazinyl)-27-methoxy-2,4,16,20,22,24,26-heptamethyl-2,7-(epoxypentadeca[1,11,13]trienimino)-6H-benzofuro[4,5-a]phenoxazine-1(2H),6,15-trione-25-acetate; 3'-hydroxy-5'-(4-isobutyl-1-piperazinyl)benzoxazinorifamycin; KRM-1643.  $C_{51}H_{74}N_4O_{11}$ ; mol wt 941.07. C 65.09%, H 6.85%, N 5.95%, O 22.10%. Semisynthetic derivative of rifamycin S. Prepn: T. Yamane et al., *EP* 366914; *idem*, US 4983602 (1990, 1991 both to Kanagafuchi); *idem*, *Chem. Pharm. Bull.* 41, 148 (1993). Antimycobacterial efficacy in comparison with rifampin, q.v.: T. Yamamoto et al., *Antimicrob. Ag. Chemother.* 40, 426 (1996). Pharmacokinetics: K. Hosoe et al., *ibid.* 2749. HPLC determ in biological fluids: *idem*, *J. Chromatog. B* 653, 177 (1994).

